Mesalamine rectal Suppositories (Canasa)

New Start/Renewal		
1. Is the patient being treated for a funded condition by the Oregon Health Plan?	Yes: Move to #2	No: Category 1 denial.
2. Does member have a diagnosis of active mild to moderate active ulcerative proctitis? a. Disease is limited to the rectum b. Mild: ≤ 4 stools per day with or without blood, no signs of systemic toxicity, and a normal erythrocyte sedimentation rate. Mild crampy pain, tenesmus and periods of constipation are also common. c. Moderate: Frequent, loose, bloody stools (> 4 daily), mild anemia not requiring blood transfusions, and abdominal pain that is not severe. Minimal signs of toxicity, including a low grade fever. Nutrition is maintained and weight loss is not associated.	Yes: Move to #3	No: Category 3 denial.
3. Is medication intended for short-term use? *Rational: Safety and efficacy beyond 6 weeks has not been established*	Yes: Move to #4	No: Forward to MD to evaluate for medical appropriateness
4. Has member tried and failed preferred formulary option mesalamine rectal enema?	Yes: Approved for 6 weeks	No: forward to MD to evaluate for medical appropriateness

Tumor Necrosis Factor

Requests for J-code medications in this class with equivalent options for self-administration require trial of self-administered drug first.

TNF Inhibitors: Formulary options		
New Start		
1. Is the patient being treated for a funded condition by the Oregon Health Plan?	Yes: Move to #2	No: Category 1 denial.
2. Is the medication being prescribed or in consultation with a gastroenterologist?	Yes: Move to #3	No: Forward to MD for medical appropriateness evaluation.
3. Does the member have a history of recurring infections or an active infection?	No: Move to #4	Yes: Forward to MD for medical appropriateness evaluation

4. Does the member have any of the following exclusions: a. Pregnant or breastfeeding b. Multiple sclerosis c. Active malignance d. Severe CHF	No: Move to # 5	Yes: Forward to MD for medical appropriateness evaluation
5. Have appropriate labs been completed to demonstrate member does not have latent or active tuberculosis or is a carrier of Hepatitis B virus?	Yes: Move to #6	No: Forward to MD for medical appropriateness evaluation
6. Does the member have a diagnosis of severe fistulizing Crohn's disease?	If Yes: Approved for 6 months	In No: Move to question #6
7. Has the member had a trial and failure or contraindication to an appropriate regimen of first-line therapy based on the indication for treatment? **Moderate to Severe Ulcerative colitis:** symptoms despite treatment for at least 12 weeks with a combination of topical therapy ***and*** the following oral therapies at maximally tolerated doses a. Oral Aminosalicylates i. Salfasalazine 4-6 grams per day ii. Mesalamine 2-4.8 grams per day iii. Basalazine 6.75 grams per day b. Oral prednisone 40-60mg per day c. Immunosuppressant i. Azathioprine 1.5mg/kg/day ii. 6-mercaptopurine 1-1.5mg/kg/day **Moderate to Severe Crohn's Disease:** Symptoms despite treatment with first line therapy with at least one agent from each of the following categories a. Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following: • Prednisone 40-60mg daily • Oral budesonide 9mg daily	If Yes: Approve for 6 month trial	No: Forward to MD for medical appropriateness evaluation

b. Aminosalicylic acid derivatives • Sulfasalazine • mesalamine c. 12 week trail of one of the following therapies: • Azathioprine 2-3mg/kg/day • 6-mercaptopurine 1-1.5mg/kg/day • Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)		
Continuation of Therapy		
1. Is member using biologic for the treatment of Ulcerative Colitis?	Yes: Move to question #2	No: Move to question # 4
2. Has the member demonstrating 80% or greater adherence to biologic and non-biologic therapy for treatment?	Yes: Move to question #3	No: Forward to MD for medical appropriateness evaluation
3. Has the member demonstrated a significant response including the following: a. Decrease in bloody stools per day and/or b. Elimination of signs of toxicity	Yes: Approve for 12 months	No: Forward to MD for medical appropriateness evaluation
4. Is the member using biologic therapy for the treatment of Crohn's disease?	Yes: Move to question #5	No: If for condition other the UC or Crohn's see appropriate criteria
5. Has the member demonstrated adherence to biologic and non-biologic therapy?	Yes: Move to question #6	No: Forward to MD for medical appropriateness evaluation
6. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?	Yes: Approve for 12 months	No: Forward to MD for medical appropriateness evaluation

**Approval of non-formulary TNF inhibitors require documentation demonstrating member meets existing PA criteria for this drug class, medication is being used for FDA indicated use within approved dosing limits and 12 week trial and failure or adverse reaction to formulary options.

Vedolizumab (Entyvio)—processing under medical benefit: J3380

New Start		
1. Is the patient being treated for a funded condition by the Oregon Health Plan?	Yes: Move to #2	No: Category 1 denial.
2. Is the medication being prescribed or in consultation with a gastroenterologist?	Yes: Move to #3	No: Forward to MD for medical appropriateness evaluation.

3. Is the medication intended for the treatment of moderate to severe ulcerative colitis or Crohn's disease?	Yes: Move to #4	No: Category 3 denial.
4. Is the member over the age of 18?	Yes: Move to #5	No: Category 3 denial.
5. Does the member have a history of recurring infections or an active infection?	No: Move to #6	Yes: Forward to MD for medical appropriateness evaluation
6. Does the member have any evidence of liver injury?	No: Move to #7	Yes: Forward to MD for medical appropriateness evaluation
7. Member will **not** be on concurrent therapy with another TNF inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria? • Antibody testing should be included that shows resistance to TNF-inhibitor options	Yes: Move to #8	No: Category 3 denial. Medication is not indicated for concomitant use with another biologic.
1. Has the member had a trial and failure or contraindication to an appropriate regimen of first-line therapy based on the indication for treatment? **Moderate to Severe Ulcerative colitis:** symptoms despite treatment for at least 12 weeks with a combination of topical therapy ***and*** the following oral therapies at maximally tolerated doses a. Oral Aminosalicylates • Salfasalazine 4-6 grams per day • Mesalamine 2-4.8 grams per day • Basalazine 6.75 grams per day b. Oral prednisone 40-60mg per day c. Immunosuppressant • Azathioprine 1.5mg/kg/day • 6-mercaptopurine 1-1.5mg/kg/day **Moderate to Severe Crohn's Disease:** Symptoms despite treatment with first line therapy with at least one agent from each of the following categories a. Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following:	If Yes: Move to #9	No: Forward to MD for medical appropriateness evaluation

• Prednisone 40-60mg daily • Oral budesonide 9mg daily b. Aminosalicylic acid derivatives • Sulfasalazine • mesalamine d. 12 week trail of one of the following therapies: • Azathioprine 2-3mg/kg/day • 6-mercaptopurine 1-1.5mg/kg/day • Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)		
8. Member has had an trial and failure to TWO preferred TNF alpha inhibitors (Humira, Remicade) for at least 12 weeks or intolerance or a contraindication to use	Yes: Move to #9	No: Forward to MD for medical appropriateness evaluation
9. Prescribed regimen is within the FDA-approved dosing regimen of 300mg at 0, 2, and 6 weeks then every 8 weeks thereafter	Yes: approved for 14 week trial	No: Category 3 denial
Continuation of therapy		
1. Is member using biologic for the treatment of Ulcerative Colitis?	Yes: Move to question #2	No: Move to question # 4
2. Has the member demonstrating adherence to biologic and non-biologic therapy for treatment?	Yes: Move to question #3	No: Forward to MD for medical appropriateness evaluation
3. Has the member demonstrated a significant response including the following: • Decrease in bloody stools per day and/or • Elimination of signs of toxicity	Yes: Approve for 12 months	No: Forward to MD for medical appropriateness evaluation
4. Is the member using biologic therapy for the treatment of Crohn's disease?	Yes: Move to question #5	No: Category 3 denial.
5. Has the member demonstrated 80% or greater adherence to biologic and non-biologic therapy?	Yes: Move to question #6	No: Forward to MD for medical appropriateness evaluation
6. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?	Yes: Approve for 12 months	No: Forward to MD for medical appropriateness evaluation

Natalizumab (Tysabri)—processing under medical benefit J2323

New Start

1. Is the patient being treated for a funded condition by the Oregon Health Plan?	Yes: Move to #2	No: Category 1 denial.
2. Is the medication being prescribed or in consultation with a gastroenterologist?	Yes: Move to #3	No: Forward to MD for medical appropriateness evaluation.
3. Is the medication intended for the treatment of Crohn's disease?	Yes: Move to #4	No: Category 3 denial (exception: for the treatment of MS— evaluate for medical appropriateness).
4. Is the member over the age of 18?	Yes: Move to #5	No: Category 3 denial.
5. Are the member and provider enrolled in the Tysabri Outreach Unified Commitment to Health (TOUCH) Prescribing Program?	Yes: Move to #6	No: Forward to MD for medical appropriateness evaluation
6. Does the member have a history of recurring infections or an active infection?	No: Move to #7	Yes: Forward to MD for medical appropriateness evaluation
7. Does the member have any evidence of liver injury?	No: Move to #8	Yes: Forward to MD for medical appropriateness evaluation
8. Does member have current or history of progressive multifocal leukoencephalopathy?	No: Move to #9	Yes: Forward to MD for medical appropriateness evaluation (contraindication for use)
9. Member will **not** be on concurrent therapy with a TNF inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria? • Antibody testing should be included that shows resistance to TNF-inhibitor options	Yes: Move to #10	No: Category 3 denial. Medication is not indicated for concomitant use with another biologic.
10. Has the member had a trial and failure or contraindication to an appropriate regimen of first-line therapy based on the indication for treatment? **Moderate to Severe Crohn's Disease:** Symptoms despite treatment with first line therapy with at least one agent from each of the following categories • Treatment with any of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated ***or*** member is unable to taper off of one of the following: • Prednisone 40-60mg daily • Oral budesonide 9mg daily	Yes: Move to #11	No: Forward to MD for medical appropriateness evaluation

e. Aminosalicylic acid derivatives • Sulfasalazine • mesalamine f. 12 week trail of one of the following therapies: • Azathioprine 2-3mg/kg/day • 6-mercaptopurine 1-1.5mg/kg/day • Methotrexate 20mg weekly (GI intolerance requires trial of SQ/IM at 20mg weekly dosing)		
11. Member has had an trial and failure to TWO preferred TNF alpha inhibitors (Humira, Remicade) for at least 12 weeks or intolerance or a contraindication to use	Yes: Move to #12	No: Forward to MD for medical appropriateness evaluation
12. Prescribed regimen is within the FDA dosing:	Yes: approved for 12 weeks trial with a QL of 15mL per 28 days	No: Category 3 denial
Continuation of therapy		
1. Is the member using biologic therapy for the treatment of moderate to severe Crohn's disease?	Yes: Move to question #2	No: Category 3 denial.
2. Has the member demonstrated 80% or greater adherence to biologic therapy?	Yes: Move to question #3	No: Forward to MD for medical appropriateness evaluation
3. Is member currently on chronic oral corticosteroids?	Yes: Move to question #5	No: Move to question # 4
4. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission? *Rational: Member and provider must be enrolled in REMS program (Tysabri Outreach Unified Commitment to Health—TOUCH) and treatment must be reauthorized every 6 months)*	Yes: Approve for 6 months	No: Forward to MD for medical appropriateness evaluation
5. Is there a plan in place to taper oral corticosteroids within 6 months of therapy initiation **or** concomitant corticosteroid therapy required does not exceed 3 months per year (in addition to initial corticosteroid taper)?	Yes: Approve for 3 months	No: Forward to MD for medical appropriateness evaluation